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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
1001.2246101

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Application Number	Filed
10/763,825	January 23, 2004

First Named Inventor
Jan Weber

Art Unit	Examiner
3731	Thomas M. McEvoy

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☑ attorney or agent of record.
Registration number 41,376.

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

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June 16, 2011
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

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Applicants submit that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a prima facie rejection.

Claims 28, 30-32, 36, 37, 50, 54, 56, 57, 63, and 85-95 were rejected under 35 U.S.C. §103(a) as being unpatentable over Maseda (US 6,514,237) in view of Couvillon (US 2003/0236531). None of Maseda, Couvillon, or a combination thereof appear to teach or suggest all of the elements recited in the claims. The rejection is thus an error.

Independent claim 26 includes the elements of an elongate body, an inflatable balloon, an active region that expands when exposed to an electrical potential and a passive deformable member. Neither Maseda nor Couvillon is cited as teaching a passive deformable member disposed over the elongate body and beneath the inflatable balloon, wherein activation of the active region causes the passive deformable member to expand and move at least a portion of the inflatable balloon from a substantially uninflated state to a first expanded state. Instead, the Office Action merely asserts that with the asserted combination of Maseda and Couvillon, "the strips would contain a passive deformable member 120 disposed over the elongate body and beneath the inflatable balloon." Applicants respectfully disagree. Both Maseda and Couvillon are asserted as teaching electroactive polymer strips. Neither reference appears to teach or suggest anything regarding a passive deformable member. The Office Action asserts that a combination of Maseda and Couvillon achieves a device in which the electroactive polymer strips are placed under the balloon of Maseda. No teaching or rational reason has been provided for how the combination of Maseda and Couvillon is interpreted as containing a passive deformable member. In view of the teachings of electroactive polymers in both references, Applicants do not understand the rationale behind the Office Action's conclusion. Neither Maseda nor Couvillon appear to support the conclusory statement.

The Supreme Court in *KSR Int'l Co. v. Teleflex Inc.* quotes *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) stated:

> "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness".

Emphasis added; see page 14 of the April 30, 2007 Decision. The Office Action has not provided any articulated reasoning with rational underpinning to support the conclusion of

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obviousness. The Office Action appears to be asserting that one could modify Maseda and Couvillon to achieve the claimed structure, which is clearly an improper ground for obviousness. The Court in KSR further stated:

> a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.

See page 14 of the April 30, 2007 Decision. As discussed above, none of the cited references appear to teach the claimed element of a passive deformable member disposed over the elongate body and beneath the inflatable balloon. Each of the claimed elements has thus not been shown to be known in the art. Further, the Office Action has not provided any objective reason to modify Maseda and Couvillon in the manner recited in independent claim 28, other than relying on the instant specification, which is clear error.

In the Office Action, Maseda is said to teach the elongate body, the inflatable balloon the active region, and electroactive polymer strands being incorporated into various segments of the device, including the balloon, so the device expands like and mimics a balloon, but Maseda does not teach the conductive polymer being at least partially beneath the balloon. The Office Action then asserts that it would have been obvious to have incorporated the conductive polymer strips 500 in the balloon, on the balloon, or under the balloon in order to expand the balloon, as it would be readily apparent to one of ordinary skill in the art that the balloon could be expanded by the strips with either orientation. Applicants respectfully disagree. Disposing an active region at least partially under an inflatable balloon is not obvious over Maseda. Maseda teaches, as noted by the Office Action, that the activation of the EAP strands may induce movement such as expansion. Col. 3, ll. 50-54. Maseda teaches an embodiment in Fig. 5A and col. 6, ll. 45-51 that uses EAP strips to induce a radial expansion of a second of the catheter. Significantly, Maseda teaches that such an embodiment can "expand like a balloon" but does not teach such strips actually expanding an inflatable balloon. Col. 6, l. 51. Maseda goes on to teach "for example, the balloon 118, which is also flexible, may incorporate the composite strands." Col. 8, ll. 8-9. However, Maseda does not teach that such strands expand radially or are used to inflate the balloon. Strands incorporated into the balloon may be used, for example, to change the stiffness or shape of the balloon rather than to inflate it. Moreover, Maseda teaches that a composite strand 306 may be attached to the outer tubular body substantially along its entire

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length and can be used to alter the stiffness of the tubular body. Col. 5, l. 56 – col. 6, l. 3. However, Maseda does not teach or illustrate that the strand of the embodiment causes the tubular body to become radially enlarged when activated. Thus even if Maseda teaches that it might be obvious to put an active region at least partially under the balloon, Maseda still fails to teach or suggest doing so in such a manner so as to cause radial expansion of the balloon.

Couvillon is cited for teaching actuating elements that comprise volumetrically expanding electroactive polymers. It is suggested that the modification of Maseda in view of Couvillon would be obvious because in Couvillon these strips are used to actuate a radially expanding member that has a cross-sectional shape like a balloon. Applicants respectfully disagree with this analysis. The Office Action suggests that using the actuators of Couvillon in Maseda would be obvious because of the balloon-like profile of the malecot element 104 of Couvillon. However, malecots and balloons are expanded in quite different ways. Balloons are expanded through providing pressure in their cavities, while malecots are expanded by bringing their ends closer together. Balloons of the sort used in stent delivery are typically folded around the inner elongate member when collapsed. Bringing the ends of a balloon together will simply create a differently folded balloon and not create any radial expansion. Moreover, Couvillon fails to teach any radial expansion of the actuating members, either in the Figures or in the text of the specification. The Advisory Action asserts that in the embodiment in Figure 4 of Couvillon, the electrically actuated members would radially expand in a configuration that closely resembles configuration 500 in Maseda. Applicants respectfully disagree. In both Maseda and Couvillon, the electrically actuated members extend longitudinally and would thus be expected to expand longitudinally or axially. A similar configuration is shown in Figure 7A of Couvillon, which shows actuators 110a longitudinally contracted and 110b longitudinally expanded. Figure 7B shows actuators 110a longitudinally expanded and 11b longitudinally contracted (and malecot element 104 expanded). In Figure 7A and likewise in Figure 7B, actuators 110a and 110b are the same width. If there was any radial expansion of the actuators, these figures would show some difference in relative width of the actuators. No radial expansion is taught with respect to the embodiments of Figures 10a, b and c either. Thus, one would not use the actuators of Couvillon in Maseda for at least two reasons. First, longitudinally expanding and contracting actuators would not radially expand a balloon. And second, the actuators of Couvillon do not

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radially expand. For at least these reasons, the rejection is an error, and claim 28 is believed to be patentable over the cited art.

Additionally and with particular regard to independent claim 50: Maseda discloses a conventional balloon catheter expanded via an inflation lumen and also discloses, as discussed above, an EAP strip configuration that can expand like a balloon. Maseda fails to suggest combining the two into a balloon that can be partially expanded using electrically actuated members and then further expanded using inflation media as claimed. Maseda might suggest the substitution of EAP elements for a balloon but fails to teach or suggest supplementing the conventional inflation media means for expanding a balloon with EAP elements. For this reason as well as for those reasons discussed above with respect to claim 28 pertaining to Maseda, the rejection is an error and claim 50 is likewise believed to be patentable over the cited art.

As claims 30-32, 36, 37, 54, 56-57, 63, and 85-95 depend from one of claims 28 and 50 and contain additional elements, Applicants submit that these claims are allowable for at least the above reasons. Further, with regard to claims 87-93: several additional objections to the rejections arise. With regard to claims 87-90: These claims are rejected off a combination of Maseda and Figs. 10a and 10c of Couvillon. These figures are diagrammatic views of actuating members according to Couvillon, and in both of them, there is an intervening layer 120. Thus, if one makes the proposed modification, the limitation of claim 50, from which claims 87-90 depend of "such that the outer surface of the one or more electrically actuated members contacts the inner surface of the inflatable balloon" is not met.

Further, with regard to claims 87-93: paragraph 74 is cited for teaching that electrodes 118 can be considered radiopaque bands. This paragraph supports the assertion that the electrodes may be radiopaque, but does not support that they are in the form of a band. A band is a piece of material in the form of a hollow cylinder open on both ends. The electrodes are not such. In Figs. 7A and 7B, for example, actuators 110a and actuators 110b are taught. Thus no single actuator encircles the tubular member.

Further, claim 87 recites "wherein a first active region is disposed over a first conductive radio-opaque band and wherein a second active region is disposed over a second conductive radio-opaque band that is positioned distal to said first conductive radio-opaque band." Fig. 10

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discloses a single conductive radiopaque band 118 disposed over a first active region 112, but none of the embodiments disclose the reverse: an active region disposed over a radiopaque band.

Further, claim 90 recites "wherein the proximal marker and the distal marker are configured to have an outer diameter that is greater than the outer diameter of the one or more electrically actuated members when the one or more electrically actuated members are in a non-activated state." Fig. 10C is the only figure in which more than one electrode 118 is taught (and thus arguably meeting the language of proximal and distal markers), and this figure clearly shows that the one or more electrodes 118 are not configured to have an outer diameter greater than that of the one or more electrically actuated members when in a non-activated state. They have the same thickness. Further, none of these actuators are in the form of a circle or cylinder and thus do not even have diametral dimensions.

Further, and with regard to claim 91: this claim recites "a first marker slidably disposed about the elongate body and engaged to the active region; and a second marker fixedly disposed about the elongate body, and wherein the passive deformable member is disposed between the proximal marker and the distal marker." In the Office Action, a proximal electrode 118 is considered to be the first marker and a distal electrode 118 is considered to be the distal marker. However, none of the electrodes are at the adhesive regions 118, where there is no movement of the actuator with respect to the tubular member. One electrode therefore has some longitudinal movement and the other electrode has more longitudinal movement when the actuator is activated. There is consequently no reasonable basis so far as Applicants can see for considering one electrode "fixed" and one electrode "slidable." When the actuator is activated, they both slide along the tubular member, albeit for different distances.

Further and with regard to claim 92: this claim recites "wherein said active region causes said passive deformable member to expand in at least one radial dimension by sliding the first marker along the elongate body towards the second marker." Emphasis added. There is a causal link between the two phrases; it is not merely that they both happen to occur. If in the embodiment of Figure 10C (again, this is the only figure that arguably has first and second markers as required), somehow, one could slide an electrode 118 without activating the actuator as a whole, the passive deformable member 120 would not be affected. For these additional reasons, as well as those discussed above, the rejections are errors.